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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	09/423,042	GUY ET AL.	
	Examiner	Art Unit	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-9,11,14,15,18,25,37-40 and 43-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-9,11,14-15,18,25,37-40,43-47* is/are rejected.

7)☒ Claim(s) *14-15, 18,39, 45-46* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 5-9,11,14-15,18,25,37-40,43-47 are pending .

Claims 11 and 43-44 stand withdrawn from consideration.

Claims 5-9, 14-15, 18, 25, 37-40, and 45-47 are under consideration.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 2, 2007 has been entered.

Objections/Rejections Withdrawn

1. The scope of enablement rejection over claims 25,37-40,42,45-47 under 35 U.S.C. 112, first paragraph (scope of enablement and written description) herein withdrawn in light of the cancellation of dependent claim 42 which broadly recited the terms antigen, peptide and DNA molecules.
2. Rejection Withdrawn over Claims 25, 37, 38,39-40, 42 and 47 under 35 U.S.C. 102(b) as being anticipated by WO96/31235 in light of the English version US Patent No 6,126,938 in light of the fact that claim 25 has been amended to recite "in an initial immunization", thus obviating the applied prior art rejection.
3. Claim 25, 37-40,42, 46 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-15 of U.S. Patent No. 6,585,975 is herein withdrawn in light of the cancellation of claim 42.

Rejections Maintained/Response to Arguments

4. Applicant's arguments filed November 2, 2007 have been fully considered but they are not persuasive.

5. The rejection of claims 5-6, 14-15, 18, under 35 U.S.C. 102(b) as being anticipated by WO96/31235 in light of the English version US Patent No 6,126,938, is traversed on the grounds "Applicants submit that the addition of different routes of administration *could be* considered as changing the basic characteristics of the method" and asserts that vaginal and rectal routes are mucosal, and not systemic.

6. In response to Applicant's assertion that a vaginal or rectal route of administration would not stimulate a systemic immune response, US Pat. 5,877,159, Powell et al , is being cited to show that mucosal administration of an immunogen will stimulate a systemic immune response (see col. 14, lines 34-36). Applicant's definition at page16, lines 2-4 is not a limiting definition that explicably states by "systemic route" we mean, but states that the systemic route "can be the parenteral route", thus permitting additional routes for obtaining a systemic immune response through other modes of administration known to one of skill in the art. At page 19, line 27, the instant Specification, Applicant sets from embodiments of the invention to include mucosal immunization administered intragastricly, rectally, and vaginally.

7. It is the position of the examiner that the claims require the stimulation of a systemic immune response (Instant claim 5 "systemic route"), the administration being subdiaphragmatic (below the diaphragm). The immune response stimulated must be prophylactic, and stimulated by a Helicobacter pylori polypeptide antigen. Based upon the recited claim limitations, these are the critical elements of Applicant's invention, and define the basic and novel characteristics of Applicant's claimed invention.

8. The claims encompass the administration of the immunogenic composition by more routes of administration than just parenteral, as the claims permit stimulation of a systemic

immune response at any location subdiaphragmatic Any type of immunization protocol that is consistent with these claim limitation would not change the basic and novel characteristics of what is claimed. Both parental and mucosal immunization steps are encompassed by independent claim 5, as long as the administration results in stimulating an immune response at a subdiaphragmatic location that is systemic.

(Instant claims 5-6, 14 and 18) Consistent with the recited claim limitations of independent claim 5, WO96/31235 discloses a method that administers the Helicobacter pylori polypeptide composition by the dorsolumbar route [0041] which is a systemic subdiaphragmatic route of administration.

This disclosed embodiment also meets the claim limitations set forth in claim 14 that requires the antigen to be administered by the strict systemic route. Guy et al disclose targeting the celiac nodes for the stimulation of a systemic subdiaphragmetic immune response by administering the composition by the dorsolumbar region intramuscularly rather than by a subcutaneous route (see [0041]): "The choice of injection site and route will depend, in particular, on the lymph nodes which it is desired to target. It may be noted that if it is desired, for example, to **target the coeliac nodes,** it is preferable to perform the injection in the **dorsolumbar region** using the intramuscular route (rather than the subcutaneous route**".** (Instant claim 15) Guy et al teach the administration of the Helicobacter pylori polypeptide by additional systemic routes of administration to include intravenous, intramuscular, intradermal or subcutaneous injections.

9. Administration of a Helicobacter pylori polypeptide composition by a subdiaphragmatic systemic mucosal route, is disclosed by Guy et al that anticipates independent claim 5:

10. [0043] "Brief Summary Text (43): The oral route, including the intragastric route, should enable the inducing agent (antigen) to reach predominantly the mucosae of the lower regions (digestive tract and mainly the small intestine and the Peyer's patches)," [0049]" In the case of the intestine or the urogenital system, the third inducing agent will advantageously be formulated for administration via the urogenital route, for example in the form of a vaginal capsule, or via the rectal route, for example in the form of a suppository." (see '938, col. 6, line 27)

11. The instant Specification provides support for the term "parenteral" which would remove any lack of clarity as to what mode of administration is being carried out in independent claim 5, if that is the scope Applicant intends. The recitation of the term "systemic" includes both parenteral and mucosal modes of administration.

12. Therefore the modes of administration of Helicobacter pylori polypeptide of Guy et al WO96' are clearly within the scope of the instant claims, and do not change the basic and novel characteristics of the claimed invention because the polypeptide, the source of the antigen, the route of administration, the mammal and the type of immune response stimulated are the same or equivalent as what is now claimed. Guy et al still anticipates the instantly claimed invention as now claimed.

13. ***Maintained, Claim Rejections - 35 USC § 102***: The rejection of claim 5 under 35 U.S.C. 102(b) as being anticipated by Fulginiti et al (1995) in light of evidence provided Chen et al (1993) and Meyer et al (EP 0835928 (see abstract)) is traversed on the grounds that Fulginiti et al does not administer a polypeptide antigen as required by the claims.

14. It is the position of the examiner that Fulginiti et al carried out more than one immunization method, one being administration of Helicobacter pylori urease expressing Salmonella which stimulated both serum (systemic) and mucosal IgA and IgG antibodies specific to urease in and ELISA. The Helicobacter pylori urease polypeptide was administered intragastrically to the mammal in an effective amount to stimulate an immune response; the polypeptide was delivered by the Salmonella AroA host cell intragastrically for stimulation of an immune response.

15. An additional embodiment disclosed in Fulginiti et al is the intraperitoneal administration of purified Helicobacter pylori native urease admixed with a cholera toxin adjuvant ; a subdiaphragmatic, systemic route of administration.

Meyer et al (EP 0835928 (see abstract)) provides evidence that the administered composition of Fulginiti would induce a protective immune response, because Meyer et al also produced and administered an aroA mutant strain of Salmonella (see page 17, claims 1-4) that expresses Helicobacter urease and the strain(s) are described by Meyer et al as inducing a protective immune response (mucosal) . Additionally, Chen et al (1993) provides evidence that the Fulginiti et al composition would induce a protective immune response based upon "intraperitoneal" administration of a Helicobacter antigen, because Chen et al administered Helicobacter antigen intraperitonelly, and found 55% protection upon challenge . Therefore Fulginiti et al still inherently discloses the instantly claimed method.

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67

USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004). "[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); Abbott Labs v. Geneva Pharms., Inc., 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999).

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

16. ***Maintained***, The rejection of claims 5-6 under 35 U.S.C. 102(e) as being anticipated by Michetti et al (US Pat. 6,290,962; filing date February 23, 1994) in light of evidence provided by Guy et al (1997) is traversed on the grounds that Michetti et al administered a Helicobacter composition by rectal mucosal administration and the instant claims require subdiaphragmatic systemic routes of administration.

17. Based upon Applicants own Specification permitting rectal administration in the methods of the claims, as described at page 19, line 27, this rejection is being maintained. Mucosal and parenteral modes of administration are permitted in the method of claims 5-6 (see page 19, lines 25-28 bridging to page 20, line 1).

18. Rectal administration is subdiaphragmatic mode of administration, and the type of immune response induced comprised a systemic immune response in light of the fact that Michetti et al found serum antibodies (see Figure 2 and Description of the Drawings) "FIG. 2 is a graphic representation of the results from Table 1 of tests for antibodies in serum (IgG) and intestinal secretion (IgA) in mice that were protected after immunization with urease." Michetti et al still inherently anticipate the instantly claimed invention as now claimed.

1. ***Obviousness-type Double Patenting*** The rejection of claims 5-9, 14-15, on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,126,938 (common inventor Bruno Guy) is traversed on the grounds that '938 administers DNA and not the polypeptide antigen of the claims.

19. It is the position of the examiner that 6,126,938 administers H.pylori urease (see claims 8-9 and claims 10-11)) intragastically, the antigen being a protein, which is a polypeptide (third agent), as well as administers by a systemic route (claim 26, a first product) a protein antigen which is claimed to be H.pylori apoenzyme urease, a protein being a polypeptide, that is administered by a parental systemic route; the first product formulated and parenterally administered, by subcutaneous, intradermal or intramuscular administration and the location of the parenteral administration is (see allowed claims 27-28) defined to include dorsolumbar region for injection (see US Pat. 6,126,938, col. 5, lines 8-17). The allowed species anticipates the instantly claimed genus of methods as now claimed. 6,126,938 still anticipates the instantly

claimed invention as now claimed. . Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed methods are directed to a species of the instantly claimed genus of methods that administer by the sub-diaphragmatic, systemic route, and the allowed method claims include the methods step of urogenital administration (see allowed claim 5) or intragastric administration (see allowed claim 9) as well as parenteral administration to the dorsolumbar region by intramuscular administration (see claims 27-28)

20. The rejection of claim 5-8 and 18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,576,244 (common inventors with instant Application: Weltzin and Bruno Guy) is traversed on the grounds that the '244 patent does not mention administration by "subdiaphragmatic, systemic routes" as required by the claims and the instant claims do not include an adjuvant.

21. With respect to the allowed claims requiring an adjuvant and the instant claims do not, the instant claims do not exclude compositions that comprise an adjuvant, and the instant Specification teaches the combination of the Helicobacter pylori polypeptides in combination with an adjuvant (see at least page 19 of the instant Specification). Therefore, the allowed method is directed to a species within the instantly claimed genus of methods, because the allowed claims are a species within the instant genus of methods.

22. It is the position of the examiner that Applicant defines the systemic route to include "the subcutaneous route, the intramuscular route and the intradermal route (see instant claim 18)". US Pat. 6,576,244 administers a composition by a subcutaneous (allowed claim 5) or intradermal

route(allowed claim 6), the subcutaneous route being defined in US pat. 6,576,244 to be the lower back (see col. 9, lines 8-14) and the intradermal route being defined to include skin of the back (see '244, col. 9, lines 14-19). The allowed species still anticipates the instantly claimed genus of methods as now claimed.

23. The rejection of claim 5 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, (UreA and UreB are defined to be Helicobacter pylori antigens (see Spec. col. 11, lines 62-63), 13 (mucosal: defined to include anal, vaginal and intragastric , col. 14, lines 19-20), 15 (Intragastrically) and 18 (prophylactic) of U.S. Patent No. 6,379,675, is traversed on the grounds that '675 requires the administration of OSP antigens which are B. burgdorferi lipoproteins in contrast to the H.pylori antigens of the present claims.

24. It is the position of the examiner that the methods of '675 administer Helicobacter pylori antigen by a sub-diaphragmatic, systemic route, wherein the method of US 6,379,675, is able to induce strong circulatory immune responses of IgG and IgA in the serum (see col. 13 ,lines 25-26) directed to Helicobacter pylori UreA and UrB antigens. While it is true that method administers a composition that includes an OspA antigen and an adjuvant, the allowed method also administers Helicobacter pylori polypeptide antigen (allowed claim 1 "UreA" and "UreB". The allowed method is a species encompassed by the instantly claimed genus of methods that administers any Helicobacter polypeptide. The allowed species anticipates the instantly claimed genus.

New Grounds of Rejection

Claim Objections

25. Claims 14, 15, 18 and 45-46 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 14-15, 18 and 45-46 administer an antigen, which is defined in the instant to be any immunogenic agent, which is broader in scope than the species of polypeptide antigen of independent claims 5 and 25 from which claims 14-15, 18 and 45-46 depend.

26. Claim 39 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 39 is of the same scope as claim 25 from which it depends, as the function limitations set forth in claim 39 are already recited in claim 25; claim 39 is not further limiting of claim 25. .

Claim Rejections - 35 USC § 112

27. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

28. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

29. Claims 7 recites the limitation "wherein a TH-type immune response and a TH2- type immune response" in dependence upon claim 6 which only recites the term “Th1-type immune response”; the term “TH2-type lacks antecedent basis in claim 6 from which it depends. There is insufficient antecedent basis for this limitation in the claim.

Please Note: In light of reconsidering the scope of the claims, the following scope of enablement is being reinstated.

1. Claims 5-9, 14-15, 18, 25, 37-40, and 45-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for induction of an immune response to a Helicobacter pylori polypeptide, and induction of an immune response for reducing the degree of infection (number of colonies) , does not reasonably provide enablement for the administration of any immunogenic agent (any polypeptide) in a method of preventing or treating Helicobacter infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in Scope with these claims.

The claimed invention is directed to the use of any Helicobacter immunogenic polypeptide that is defined by function and required to have any specific structure other than an epitope that will stimulate an immune response in a method of preventing or treating Helicobacter infection in any mammal through the administration of the agent to a mammal. Tomb et al in 1997 showed Helicobacter pylori to encode 1590 polypeptides, and states that the number of potential proteins underscores the potential complexity of host-pathogen interactions (see abstract).

While the immunogenic agents, by definition, would induce an immune response, polypeptide is any Helicobacter polypeptide that will induce an immune response in any mammal. The immune response need not be a long lasting immune response, nor is the immunogen combined with a pharmaceutical carrier or adjuvant for induction of an enhanced immune response to reduce infection.

The specification does not provide substantive evidence that any immunogenic polypeptide Helicobacter pylori would provide for prevention or treatment of Helicobacter infection.

Data obtained from challenge experiments must demonstrate an art recognized standard of improvement over the control in order for the composition to be considered as being useful for treating or preventing infection and disease. This information is essential for the skilled artisan to be able to use the claimed immunogenic agents for their intended purpose of treating or preventing *Helicobacter* infection. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed immunogenic agents, i.e. would not be able to accurately predict if protective immunity has been induced. Patients with H.pylori infection produce a diagnostic immune response that is not therapeutic as infection persists.

The prior art teaches that Helicobacter pylori vaccines are unpredictable, specifically, in the type of effect they will have on preventing or treating infection. The ability to reasonably predict the capacity of a single bacterial immunogen, to induce protective immunity is problematic.

In HP WORLD-WIDE, a publication from Brocades Pharma BV Leiderdorp, The Netherlands, February 1992, data was presented stating that immunization does not appear promising. Parenteral immunization of specific pathogen free mice with *H. felis* gave no protection against gastric colonization; previous oral infection only delayed colonization (Heap,K, Australia). The article also taught that "although intra-peyers patch immunization of killed *H. pylori* in rats shows that the gut mucosa can mount a vigorous immune response, oral immunization with either live or killed bacteria induced no significant serum or salival antibody response (Dunkley, M, Australia). Blaser also warned that because of the possible autoimmune component of the disease the wrong vaccine could actually make things worse."

Unfortunately, the vaccine art is replete with instances where even well characterized immunogenic agents that induce a neutralizing antibody, defined by in vitro assay, fail to elicit in vivo protective immunity (Boslego). Merely because an immune response can be stimulated to a Helicobacter immunogenic agent, does not define the immunogenic agent as an agent for preventing or treating Helicobacter infection. Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful immunogenic agent vaccine without the prior demonstration of vaccine efficacy.

It is known it the art that vaccines convey protection from infection and disease. Rappuoli et al (European Journal of Gastroenterology and Hepatology, 1993, Vol.5, (suppl. 2) pages 576-578) teach that development of a vaccine against *Helicobacter pylori* would involve four major steps:

1) identification of the factors required for virulence;

2) large-scale production and characterization of the virulence factors;

3) development of appropriate animal models to test the virulence and immunogenicity of the molecules identified; and

4) identification of the type of immunity able to prevent infection and disease.

Alashli et al (Digestive Disease 2001, abstract) states that despite intensive research to develop vaccine therapy for Helicobacter pylori, and addresses animal model successes and failures and the limited experience with human vaccines, and states there are obstacles to obtaining an H.pylori vaccine. Additionally, Seppala et al (1995) states that the world is still waiting for a better treatment option for the most common infection (abstract).

Given the lack of guidance on how to obtain the desired effect using an immunogenic agent comprising any immunogenic agent in a method of treating or preventing *Helicobacter* infection, and in light of the teachings of the prior art which teaches that vaccines comprising Helicobacter polypeptides, and the instant claims only defining the administered compositions by function and relative optical density units in an ELISA assay, and not be structure correlated with function, the induction of a protective immune response would be unpredictable in methods of treating or preventing infection and the skilled artisan could not make and use the claimed invention. No working examples are shown which convey the missing information. Therefore, the skilled artisan could not use **any** Helicobacter polypeptide to obtain the desired effect of preventing or treating infection without undue experimentation.

Claim Rejections - 35 USC § 102

30. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

31. Claims 25, 37-40, 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al (WO97/02835, publication date January 10, 1997).

Thomas et al disclose the instantly claimed method, the method comprising the steps of:

Mucosally (see WO97', page 2, lines 13-17 "mucosal (e.g., intranasal, oral, ocular gastric, rectal, vaginal, gastrointestinal, or urinary tract) administration may precede parenteral (e.g., intravenous, subcutaneous, intraperitoneal, or intramuscular) administration") administering to a mammal (see page 4, line 2 "humans,) in an initial immunization, an effective amount (see page 7, lines 8-11) of Helicobacter pylori (see page 2, line 28) polypeptide antigen (see page 2, lines 25-26; page 7, line 19) and then

Parenterally administering an effective amount of Helicobacter pylori polypeptide antigen (see page 2, lines 23-27) to said mammal (see page 2, lines 15-17).

Instant claim 37: further comprising carrying out more than one mucosal administration (see page 2, lines 18-22 "three weekly doses may be administered mucosally" and on the fourth week, combined mucosal and parenteral administration may be carried out) .

Instant claim 38: further comprising carrying out more than one parenteral administration (see page 11, lines 6-10: "first dose of the vaccine can be administered to a mucosal" surface, and "booster immunization can be administered parenterally"; page

11, lines 23-26, "Administration is repeated as necessary, as can be determined by one skilled in the art. For example, a priming dose can be followed by 3 booster doses at weekly intervals").

Instant claim 40: the mucosal administration is oral (see page 2, lines 13 "oral").

Instant claim 45: administering a mucosal adjuvant in combination (see page 11, lines 15-16 "co-administered") with the Helicobacter pylori antigen (see page 10, lines 19-22).

Instant claim 46: administering a parenteral adjuvant in combination (see page 11, lines 15-16 "co-administered") with the Helicobacter pylori antigen (see page 10, lines 22-24).

Instant claim 47: wherein the parenteral administration is intramuscular (see page 2, line 17) or subcutaneous (see page 11, line 10)

Thomas et al anticipate the instantly claimed invention as now claimed**.**

Conclusion

This is a non-final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
February 29, 2008

/Mark Navarro/
Primary Examiner, Art Unit 1645